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THE UNITED STATES PHARMACOPEIAL CONVENTION
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the percentage of each impurity in the portion of Amphetamine Sulfate taken by the formula:

$$10{,}000(C/W)(r_i / r_S)$$

in which C is the concentration, in mg per mL, of USP Dextroamphetamine Sulfate RS in the *Standard solution;* W is the weight, in mg, of Amphetamine Sulfate taken to prepare the *Test solution;* r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the peak response for amphetamine obtained from the *Standard solution:* not more than 0.1% of any individual impurity is found, and not more than 0.5% of total impurities is found.

Organic volatile impurities, *Method I* ⟨467⟩: meets the requirements.

(Official until July 1, 2008)

Assay—Dissolve about 500 mg of Amphetamine Sulfate, accurately weighed, in 50 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 36.85 mg of $(C_9H_{13}N)_2 \cdot H_2SO_4$.

Amphetamine Sulfate Tablets

» Amphetamine Sulfate Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $(C_9H_{13}N)_2 \cdot H_2SO_4$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—*USP Dextroamphetamine Sulfate RS.*

Identification—Macerate a quantity of powdered Tablets, equivalent to about 50 mg of amphetamine sulfate, with 10 mL of water for 30 minutes, and filter into a small flask. To the filtrate add 3 mL of 1 N sodium hydroxide. Cool to about 10° to 15°, add 1 mL of a mixture of 1 volume of benzoyl chloride and 2 volumes of absolute ether, insert the stopper, and shake well for 3 minutes. Filter the precipitate, wash with about 15 mL of cold water, and recrystallize twice from diluted alcohol: the crystals of the benzoyl derivative of amphetamine so obtained, after drying at 80° for 2 hours, melt between 131° and 135°, the procedure for *Class I* being used (see *Melting Range or Temperature* ⟨741⟩).

Dissolution, *Procedure for a Pooled Sample* ⟨711⟩—

Medium: water; 500 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Mobile phase—Dissolve 1.1 g of sodium 1-heptanesulfonate in 575 mL of water. Add 25 mL of dilute glacial acetic acid (14 in 100) and 400 mL of methanol. Adjust by the dropwise addition of glacial acetic acid to a pH of 3.3 ± 0.1, if necessary, filter, and degas the solution. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph replicate injections of the Standard solution, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

Procedure—Inject a volume (about 500 µL) of a filtered portion of the solution under test into the chromatograph, record the chromatogram, and measure the response for the major peak. Calculate the quantity of $(C_9H_{13}N)_2 \cdot H_2SO_4$ dissolved in comparison with a Standard solution having a known concentration of USP Dextroamphetamine Sulfate RS in the same medium and similarly chromatographed.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $(C_9H_{13}N)_2 \cdot H_2SO_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Prepare as directed under *Amphetamine Assay* ⟨331⟩.

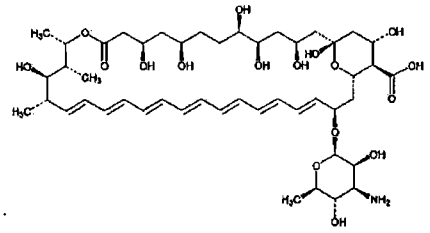
Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 5 mg of amphetamine sulfate, to a 100-mL beaker, add 2 mL of hydrochloric acid solution (1 in 100), swirl gently to wet the powder thoroughly, warm on a steam bath for about 1 minute, with occasional gentle swirling, and cool. Add 3 g of purified siliceous earth, and mix until a fluffy mixture is obtained.

Procedure—Proceed as directed under *Amphetamine Assay* ⟨331⟩. Calculate the quantity, in mg, of $(C_9H_{13}N)_2 \cdot H_2SO_4$ in the portion of Tablets taken by the formula:

$$0.01C[(A_{U257} - A_{U280}) / (A_{S257} - A_{S280})]$$

in which C is the concentration, in µg per mL, of USP Dextroamphetamine Sulfate RS in the *Standard preparation.*

Amphotericin B



$C_{47}H_{73}NO_{17}$ 924.08

Amphotericin B.

Amphotericin B.

[1*R*-(1*R**,3*S**,5*R**,6*R**,9*R* *,11*R**,15*S**,16*R**,17*R**,18*S**,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R* *,35*S**,36*R**,37*S**)]-33-[(3-Amino-3,6-dideoxy-β-D-mannopyranosyl)oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,-39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid [*1397-89-3*].

» Amphotericin B has a potency of not less than 750 µg of $C_{47}H_{73}NO_{17}$ per mg, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers, and store in a cold place.

Labeling—Label it to state whether it is intended for use in preparing dermatological and oral dosage forms or parenteral dosage forms.

USP Reference standards ⟨11⟩—*USP Amphotericin B RS. USP Nystatin RS.*

Identification, *Ultraviolet Absorption* ⟨197U⟩—

Spectral range 1: 240 to 320 nm.

Solution 1: prepared as directed for *Test preparation* in the *Limit of amphotericin A,* and compare its absorbance to that of the *Amphotericin B standard preparation.* An extra peak may occur at 304 nm in the spectrum of this solution.

Spectral range 2: 320 to 400 nm.

Solution 2: prepared as directed for *Test preparation* in the *Limit of amphotericin A* and then diluted with 9 volumes of methanol. Compare its absorbance to that of a similar dilution of the *Amphotericin B standard preparation.*

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 5.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.5%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid. [NOTE—Amphotericin B intended for use in preparing dermatological creams, lotions, and ointments, and oral suspensions and capsules, yields not more than 3.0%.]

Limit of amphotericin A—

Test preparation—Dissolve about 50 mg of Amphotericin B, accurately weighed, in 10.0 mL of dimethyl sulfoxide in a 50-mL vol-